REMARKS

Claim 1-17 and 21-26 are pending and stand rejected. Claims 3-5, 8-11, 14, 21-23, 25 and 26 are canceled herein without prejudice. Claims 1, 2, 6, 7, 12, 13, 15-17 and 24 are amended herein. In particular, claims 1, 2, 12, 13 and 15 are amended to further clarify the nature of the noncovalently interacting chiral regions on polymers (A) and (B). Support for the claim amendments is provided by the specification at, for example, page 5, lines 16-19; page 6, lines 3-10; page 10, lines 3-5; page 18, lines 1-12; and by the claims as filed. New claims 27-31 are added. Support for the new claims is provided by the specification at, for example, page 2, lines 1-3; page 4, lines 28-34; page 11, lines 11-21; page 16, lines 32-33, page 17, lines 9-12; and by the claims as filed. Accordingly, no new matter is added. Entry of the new claims and claim amendments and reconsideration is respectfully requested, in view of the following remarks. Claims 1, 2, 6, 7, 12, 13, 15-17, 24, and 27-31 are now pending.

Formal Matters

The Applicants thank the Examiner for the courtesy of a telephonic interview on December 3, 2007, to discuss the prior art rejections over the references of Okihara et al., Hennink et al., and Hakomori et. al. No agreement was reached with respect to the claims.

Rejections under 35 U.S.C. 112, first paragraph

Written description

Claims 1-14 and 21-26 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner has asserted that it is unclear how the polymer is substituted with the oligomer or co-oligomers; that "grafting" and "substitution" are not equivalent; that the specification doesn't name or show water soluble polymers substituted with oligomers or co-oligomers; that the specification doesn't name or show possession of the product of claim 21 because there is no clear choice of water soluble polymer;

that the specification does not provide a description of a releasable compound of claim 21 adequate to show possession. Applicants respectfully traverse the rejections.

As the Examiner knows, to satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991); MPEP § 2163(I). There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976); MPEP § 2163(I)(A).

Applicants respectfully submit that a person of skill in the art would understand how the claimed hydrophilic polymers are "substituted" with oligomers or co-oligomers based on the description and examples provided. Nevertheless, solely to facilitate prosecution, claims 1 and 15 are amended to replace the term "substituted" with "grafted."

The specification provides working examples of specific hydrogel compositions comprised of water soluble or water dispersible hydrophilic polymers grafted with oligomers or co-oligomers, as claimed. *See* specification at, e.g., Examples 1, 2, 4 and 6. Thus, a person of skill in the art could reasonably conclude that the Applicants were in possession of the claimed invention at the time of filing. Accordingly, Applicants respectfully request that the written description rejections be withdrawn.

Enablement

Claims 1-5, 7-17, and 21-26 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The Examiner has acknowledged that the specification is enabling for dextran polymer grafted with lactide, but asserts the full scope of the claims is not enabled. Applicants thank the Examiner for the indication that the enablement rejection may be overcome by amending claims 1, 5 and 15 to dextran and lactide oligomers or co-oligomers. Applicants respectfully traverse the rejections.

"To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' … Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). "A patent need not teach, and preferably omits, what is well known in the art." *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). MPEP § 2164.01.

With reference to the nature of the invention, the Office action states on page 3 that "[t]he invention is directed to all water-soluble or water dispersible polymers that are substituted with any and all oligomers or co-oligomers" (emphasis added). With regard to the breadth of the claims, the Examiner states on page 3 of the Office action that "[t]he scope of the claims is open to any water-soluble or water dispersible polymers and any and all oligomers or co-oligomers." This is simply not the case.

Claim 1 recites:

1. Hydrogel composition comprised of a mixture of

(A) a water soluble or water dispersible hydrophilic polymer grafted with oligomers or co-oligomers, wherein the oligomers or co-oligomers comprise a first chiral region, said first chiral region being mainly composed of first chiral monomers having identical chirality, and

(B) a water soluble or water dispersible hydrophilic polymer grafted with oligomers or co-oligomers, wherein the oligomers or co-oligomers comprise a second chiral region with a chirality that is opposite to the chirality of the first chiral region, said second chiral region being mainly composed of second chiral monomers having identical chirality to one another, said second chiral monomer having chirality that is opposite to the chirality of said first chiral monomers,

in an aqueous system,

such that the chiral region of the oligomers or co-oligomers in (B) are in essence complementary to the chiral region in (A), wherein the first chiral region and the second chiral region interact noncovalently.

In defining the nature of the invention and the breadth of the claims, Applicants respectfully submit that the Office has disregarded the fact that the claimed invention is a hydrogel composition in an aqueous system. The Office has likewise disregarded the claim limitations which require that the hydrogel composition is comprised of a mixture of two polymers, each grafted with oligomers or co-oligomers composed mainly of chiral monomers having identical chirality, wherein the chiral regions on the two polymers have opposite chirality and interact noncovalently.

Applicants would appreciate clarification of the Examiner's statements regarding the state of the prior art, as indicated on page 4 of the Office action. Polymers which are not water soluble or water dispersible hydrophilic polymers, or polymers grafted with oligomers which lack the required complementary chiral regions, for example, clearly do not fall within the scope of the instant claims.

Regarding the quantity of experimentation required, the Office has asserted that insufficient guidance is provided to enable all polymers and all oligomers, and that not all chiral polyesters form stereocomplexes. Applicant's respectfully note that the enablement requirement of 35 U.S.C. § 112, first paragraph does not require a complete absence of experimentation in the practice of the claimed invention. "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). MPEP § 2164.06.

"In the chemical arts, the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed." MPEP § 2164.06. In the instant case, the Applicants have provided detailed guidance for determining the rheology behavior of hydrogel samples under standard experimental conditions and using standard equipment. *See* specification at, e.g., Example 3. The Applicants have also provided typical rheograms for the exemplified compositions as well as characteristic data showing the development of storage moduli as a function of time. *See* specification at, e.g., Figures 2 and 3,

and data in Tables 1-3. In addition, the thermoreversibility and elastic properties of the claimed compositions are described. *See* specification at, e.g., page 33-34 and Figures 5-7. Accordingly, Applicants respectfully submit that sufficient guidance is provided such that the experimentation required to determine whether a particular sample forms a hydrogel composition as claimed is not undue.

The specification teaches the skilled artisan how to make and use the claimed hydrogel compositions. The synthesis, characterization and properties of specific oligomers, grafted polymers, and hydrogel compositions are described. *See* specification, e.g., Examples 1, 2, and 4. The synthetic routes provided by the Applicants are generally useful for the preparation of the claimed hydrogel compositions. *See* specification at, e.g., Example 4. The Applicants have described characteristic rheologic behavior of the claimed hydrogels, and provided specific guidance for determining rheologic behavior to assess gel formation. *See* specification at, e.g., Example 3. Moreover, the Applicants have described the protein release properties of the claimed hydrogels at, e.g., Example 5 and in Figures 12A and 12B. Accordingly, the Applicants have provided sufficient guidance such that a person of ordinary skill in the art could to make and use the invention as claimed.

In view of the guidance provided in the specification disclosing the synthesis of hydrophilic polymers grafted with oligomers or co-oligomers; the formation and characterization of hydrogels as claimed, including their characteristic rheologic behavior and protein release data; and what was already well known in the art, the Applicants submit that the claims as amended are reasonably enabled. Accordingly, Applicants respectfully request that the enablement rejections be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-14 and 21-26 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants respectfully traverse the rejections.

With regard to claim 1, the Examiner has asserted that it is unclear what is meant by "substituting" the water soluble or water dispersible polymer with oligomers. As discussed above, the term "substituted" has been replaced by "grafted." Claim 1 is further objected to as allegedly providing insufficient antecedent basis for the expression "said groups" in line 10. Claim 1 is amended to further clarify that the two polymer strands (A) and (B) are discrete polymers, and to further define the nature of the noncovalently interacting chiral regions on (A) and (B); the expression "said groups" is deleted.

With respect to claim 6, the Examiner has asserted that the terms "cellulose derivatives" and "related copolymers" of poly(lysine) and poly(glutamic acid) are not defined in the claims. Claim language is definite when the metes and bounds of the invention can be adequately determined. *In re Goffe*, 526 F.2d 1393, 1397 (CCPA 1975). Applicants note that cellulose and poly(amino acid) copolymers are well known in the field of polymer chemistry. In view of this, Applicants respectfully submit that the metes and bounds of the rejected claims are sufficiently clear to one of ordinary skill in the art.

The Examiner has asserted that claim 24 is unclear because it relates to drug delivery, but the composition of claim 1 does not contain a drug. Applicants respectfully disagree. Claim 1 uses the open-ended transition "comprised of" and therefore the claimed hydrogel composition does not exclude the inclusion of a drug. Nevertheless, solely to facilitate prosecution, claim 24 is amended to depend from new claim 31, which expressly includes a drug to be released.

The rejections related to claims 3-5, 8-11, 14, 21-23 and 25-26 are mooted by cancellation of the claims. In view of the foregoing remarks, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1-5, 7-10 and 13 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Okihara et al., *J. Macromol. Sci. Phys.* (1991) B30 (1 & 2) 119-140. Claims 1-10, 14 and 21-26 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Hennink et al., WO 98/00170.

Claim 23 is rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Hakomori et al., U.S. 5,230,900. Applicants respectfully traverse the rejections. The rejections are also traversed to the extent they apply to new claims 27-31.

The Examiner has reinstated the rejection of claims 1-5, 7-10 and 13 as allegedly anticipated by Okihara et al., and reiterates the previous assertion that the stereocomplex of Okihara et al. inherently forms a hydrogel. Applicants respectfully disagree, for reasons of record, as well as at least the following.

As has been previously explained, Okihara *et al.* do not disclose the formation of hydrogels and there is no evidence of record to support the Office's assertion that the stereocomplex described by Okihara *et al.* inherently forms a hydrogel. "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.,* 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

The Office is again invited to identify any portion of the cited art or some other available reference that supports the assertion that the allegedly inherent property of the stereocomplex of Okihara et al. is necessarily present and would be recognized by a person of ordinary skill in the art. Alternatively, Applicants invite the Office to take official notice of the allegedly inherent principle taught in Okihara *et al.* so that the record can be made complete for appeal.

The Examiner asserts on page 8 of the Office action that while the X-ray data described by Okihara et al. is from a crystalline stereocomplex, "the lactide/glycolide complex was formed or existed before crystallization of the product." However, the Office has again provided no factual basis to support the assertion that the product of Okihara et al. existed as a stereocomplex prior to crystallization. Applicant's note that it is well known in the art that molecular conformations may

change during the process of crystal packing. In addition, the Office has not explained how such a stereocomplex, even if it existed prior to crystallization, would anticipate the claimed invention.

First, as the Applicants have previously explained, poly(lactic acid) and oligo(lactic acid) are not soluble in water and do not form hydrogels (*see* Hennink Decl. I of January 20, 2005, ¶6), and it is well known in the art that poly(lactic acid) is highly hydrophobic in nature. S*ee, e.g.* Huh *et al.* Drug Delivery Tech. 2003; 3:42, left column, second paragraph, (submitted previously), which notes that "[t]he biodegradable polyesters [including PLA] are all strongly hydrophobic."

Thus, the stereocomplex of Okihara et al. does not comprise a water soluble or water dispersible hydrophilic polymer, or two such polymers, nor are they present in an aqueous system. As has been previously explained, the Okihara stereocomplex cannot form hydrogels in the absence of water. *See*, e.g., Hennink Decl. II of April 19, 2006, ¶¶ 2 and 3. The Examiner has presented no competent evidence to overcome the evidence submitted by the Applicants that the stereocomplex of Okihara et al. does not provide a hydrogel, as claimed.

The Applicants would appreciate clarification of the Examiner's comment on page 8 of the Office action that "when the polymer is substituted with oligomers, the resulting product is the oligomer." Clearly, a hydrophilic polymer grafted with an oligomer is not itself an oligomer.

Finally, the Examiner has stated on page 7 of the Office action that "lactide is a di-ester of lactic acid" with a molecular weight of about 144, and suggests that the polymer of Okihara et al. having a molecular weight of 5000 amu would translate to about 35 lactide units. Applicants call to the Examiner's attention that each molecule of lactide contributes two lactic acid "monomers" to the polymer length, and thus a polymer prepared by ring-opening polymerization of about 35 lactide units would comprise about 70 lactic acid units.

For the reasons already of record, as well as those stated above, Okihara et al. does not anticipate the claimed invention because it fails to teach each and every element of the claims. Applicants respectfully request that the rejections under 35 U.S.C. § 102(b) over Okihara et al. be withdrawn.

Claims 1-10, 14 and 21-26 remain rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Hennink et al. As noted by the Examiner, Hennink et al. disclose a biodegradable hydrogel that consists of two interpenetrating networks interconnected to one another through hydrolysable spacers, which may include poly(glycolic acid) and/or poly(lactic acid) spacers. The Examiner also notes that the hydrogel is prepared by radical polymerization; that increasing the degree of substitution yields a more cross-linked network; that the hydrogel may be loaded with drugs during polymerization or cross-linking; and that the hydrogel may be in the form of microspheres. Based on these teachings, the Examiner asserts that Hennink et al. meets the limitations of the claims. Applicants respectfully disagree, for reasons of record, as well as at least the following.

The Examiner asserts on page 9 of the Office action that "the composition claims do not exclude or include covalent or non-covalent interaction." Applicants note that the instant claims clearly and explicitly require the first and second chiral regions to interact noncovalently. By contrast, as has been previously explained by the Applicants, the hydrogels of Hennink et al. are covalently cross-linked and do not contain chiral monomers having complementary chirality; thus, the polymers described by Hennink et al. are incapable of interacting noncovalently with each other, as explicitly required by the instant claims. *See*, e.g., Hennink Decl. II of April 19, 2006, ¶¶ 6-9. The Examiner has presented no competent evidence to overcome the evidence submitted by the Applicants that the covalently crosslinked hydrogels of Hennink et al. are incapable of interacting noncovalently and hence do not anticipate the claims.

With regard to the hydrolysable spacers, the Examiner asserts on page 9 of the Office action that the spacers described by Hennink et al. "meets the limitation of the oligomers recited in claim 2, *which defines the oligomers of claim 1*." Applicants respectfully note that claim 2 is a dependent claim and does not define the oligomers of claim 1. Claim 2 necessarily includes all the limitations of claim1 from which it depends, including the requirements that the first and second chiral regions have complementary chirality and interact noncovalently. Thus, it is immaterial than Hennink et al. describe poly(lactic acid) or poly(glycolic acid) spacers, as the reference does not teach each and every element of the invention as claimed.

The Office has also asserted on page 9 of the Office action that the claimed composition "is a blend of A and B, where the hydrophilic polymer in A is not different from that in B, so that within the blend is present a racemic [mixture] of the hydrophilic polymer and the oligomers of lactic or glycolic acids." First, Applicants note that to the extent the hydrophilic polymer is itself a chiral molecule, for example, dextran, the products formed by grafting polymers (A) and (B) with chiral oligomers or co-oligomers having opposite chirality will be diastereomeric, not enantiomeric. It is well known in the art that combining diastereomers does not lead to a racemic mixture.

Second, even assuming, *arguendo*, that in certain embodiments the hydrophilic polymers (A) and (B) are enantiomeric, Hennink et al. still fail to disclose two such polymers grafted with chiral oligomers or co-oligomers whose chiral regions have opposite chirality which interact noncovalently. As noted previously, the only chiral hydrogel disclosed by Hennink et al. was formed by radical polymerization of dextran-(L-lactide)-HEMA, to give a covalently cross-linked hydrogel wherein the chiral portion of the hydrolysable spacer have the same chirality. *See* Hennink et al. at Examples 3 and 5. Thus, it is unclear how the Examiner's assertion regarding a racemic mixture, even if true, supports the conclusion that the instant claims are anticipated by Hennink et al.

Finally, the Office has asserted that claim 2 of Hennink et al. discloses that the composition comprises two interpenetrating polymer networks. *See* Office action at page 9. Claim 2 of Hennink et al. recites a "[h]ydrogel according to claim 1, consisting of two interpenetrating polymer networks *interconnected to one another through hydrolysable spacers*." The plain language of the claim requires that the polymer networks be covalently interconnected to one another. As described by Hennink et al., the polymer networks are covalently crosslinked by radical polymerization. *See* Hennink et al. at page 9, lines 14-18. Thus, claim 2 of Hennink et al. cannot anticipate the instant claims, which requires two hydrophilic polymers (A) and (B) grafted with chiral oligomers or co-oligomers whose chiral regions have opposite chirality and interact noncovalently.

For the reasons already of record, as well as those stated above, Hennink et al. does not anticipate the claimed invention because it fails to teach each and every element of the instant claims. Applicants respectfully request that the rejections under 35 USC § 102(b) over Hennink et al. be withdrawn.

The rejection of claim 23 under 35 U.S.C. § 102(b) as allegedly anticipated by Hakomori et al., U.S. 5,230,900, is rendered moot by cancellation of the claim. Applicants address the rejection over Hakomori et al. to the extent it applies to new claim 29. The Examiner asserts that Hakomori et al. disclose microsphere compositions that include lactide glycolide copolymers, polyacrolein graft copolymer, carboxymethyl dextran, or polylactide and polystyrene or combinations. *See* Hakomori et al. at column 3, lines 50-56. Hakomori et al. relates to a tumor-associated antibody or ligand coupled to a microsphere which contains a differentiation inducer. *See* Hakomori et al. at col. 3, lines 28-33. The Examiner has provided no explanation as to how the cited portion of Hakomori et al., which does not describe water soluble or water dispersible hydrophilic polymers coupled to chiral oligomers which interact noncovalently, can possibly anticipate the instant claims.

The rejections of claims 3-5, 8-10, 14, 21-23 and 25-26 are mooted by cancellation of the claims. Based on the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 102 be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 11-13 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Hennink et al., WO 98/00170. Claims 15-17 remain rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over DeJong et al., *Macromolecules*, 1998, 31:6397-6402, in view of Brannon-Peppas, *Int. J. Pharm.*, 1995, 116:1-9. Applicants respectfully traverse the rejections for reasons of record, as well as at least the following. Claim 11 is cancelled, rendering the rejection moot.

Claims 12 and 13 depend from claim 1, and necessarily contain all the limitations therein. Claim 12 as amended requires that the first chiral region comprises poly(D-lactic acid) and

the second chiral region comprises poly(L-lactic acid). Claim 13 as amended relates to a hydrogel composition according to claim 1, wherein the first chiral region and the second chiral region are comprised of 7-25 chiral monomers on average.

To establish a *prima facie* case of obviousness, the Office must provide one or more references that, *inter alia*, teach or suggest all the limitations of the claimed invention. The recent decision of the Supreme Court in *KSR v. Teleflex* re-emphasizes the requirement that the *Graham* factors be evaluated in determining whether the claimed invention is obvious. As the Office is, of course, aware, the *Graham* factors require a determination of 1) the content of the prior art, 2) the level of a skill of the ordinary practitioner of the art, and 3) the nature of the differences between the prior art and the claimed invention. It must then be evaluated, as a matter of law, whether these differences, in the context of the claimed subject matter as a whole, would or would not have been obvious to the skilled artisan.

The content of the prior art

With respect to the rejection of claims 12-13 as allegedly obvious over Hennink et al., the Office states that Hennink et al. teach that increasing degree of substitution (DS) yield more cross-linked network (page 9, lines 31-34); that with regard to claim 12, Hennink et al. disclose that the polymer contains one or more units of lactic or glycolic acid (page 9, line 12); regarding claim 13, that while Hennink is silent on the length of the oligomeric groups, it follows that a racemic mixture of lactic acid or glycolic acid would have equal lengths. *See* Office action at page 11-12. The Examiner asserts that it would have been obvious to one of skill in the art to prepare a hydrogel with the appropriate degree of substitution (DS) since Hennink teaches the DS is related to the extent of crosslinking.

Differences between the prior art and the claimed invention

As already discussed at length, Hennink et al. neither teach nor suggest all the limitations of the claimed invention. Hennink et al. fail to teach two hydrophilic polymers, each grafted with

oligomers or co-oligomers comprising a chiral region having complementary chirality, which interact with each other noncovalently. *See*, e.g., Hennink Decl. II of April 19, 2006, ¶¶ 7-9.

As noted above, Hennink et al. describe covalently crosslinked hydrogels which, unlike the hydrogels as claimed, do not contain oligomers having complementary chiral regions, and are thus incapable of interacting noncovalently, as claimed. *See*, e.g., Hennink Decl. II of April 19, 2006, ¶ 9. Moreover, the Examiner has provided no reason that a person of ordinary skill in the art would have replaced the covalently crosslinked polymer of Hennink et al. with the presently claimed invention.

With respect to claims 12 and 13, Hennink et al. do not describe or suggest two grafted hydrophilic polymers wherein the first chiral region comprises poly(D-lactic acid) and the second chiral region comprises poly(L-lactic acid), or hydrogels wherein the noncovalently interacting first and second chiral regions are comprised of 7-25 chiral monomers on average. As discussed above, the only chiral hydrogel described by Hennink et al. is covalently cross-linked and the chiral portions of the hydrolysable spacers have the same chirality.

The Office has failed to carry its burden to establish a *prima facie* case of obviousness of claims 12-13 over Hennink et al. Accordingly, Applicants respectfully request that the present rejection be withdrawn.

Claims 15-17 remain rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over De Jong et al. in view of Brannon-Peppas.

As noted in the memorandum from the Deputy Commissioner, issued immediately in response to the *KSR* decision, in formulating a rejection for obviousness based on a combination of elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements "in the manner claimed." The Office has provided no motivation or suggestion to combine that would lead one of skill in the art at the time of the invention to combine the references of De Jong *et al.* and Brannon-Peppas with elements not found

in either reference, in particular water soluble or water dispersible hydrophilic polymers grafted with oligomers or co-oligomers having complementary chirality, as in the instant claims.

The Examiner notes that De Jong *et al.* disclose stereocomplex formation between homo- or copolymers of poly(lactic acid), and blends of D- or L-lactide/e-caprolactone (abstract and page 6397). The MEE-lactide oligomers were formed from lactide in the presence of 2-(2-methoxyethoxy)ethanol (MEE) and stannous octoate as catalyst. *See* De Jong *et al.*, at page 6399. The Office acknowledges that De Jong et al. do not teach incorporating an active ingredient, but alleges it would have been obvious to one of ordinary skill at the time of the invention to include an active ingredient in the stereocomplexes described by De Jong *et al.* in view of Brannon-Peppas, which the Office characterizes as teaching that lactide hydrogels can be drug carriers. *See* Office action at page 12.

First, Applicants note that the stereocomplexes described by De Jong et al. are stereocomplexes between oligomers. De Jong et al. neither teach nor suggest oligomers coupled to water soluble or water dispersible hydrophilic polymers, or the formation of hydrogels, as claimed. De Jong et al. observed stereocomplex formation in the blend of an equal weight amount of D- and L- monodisperse MEE-poly(lactic acid) by differential scanning calorimetry (DSC), wherein formation of a crystalline phase is observed as a sharp melting peak in the DSC thermogram. *See* De Jong et al. at page 6400, and Figure 5. Applicants note that DSC is a technique used to study the *thermal transitions* of polymers, and is therefore performed as a melt of the polymer blend. As previously indicated in Professor Hennink's declaration, hydrogels generally contain from about 20 weight % to more than 99 weight % water, *See* Hennink Decl. II of April 19, 2006, ¶ 3. Thus, contrary to the assertions of the Office, the stereocomplexes described by De Jong *et al.* are not hydrogels, as hydrogels cannot form in the absence of water.

The failure of De Jong *et al.* to teach the preparation of hydrogels as claimed is not remedied by the combination with Brannon-Peppas, which merely describes the use of biodegradable micro-and nanoparticulate systems containing poly(lactic acid), poly(glycolic acid) or their copolymers in controlled drug delivery. Brannon-Peppas does not describe the formation of

hydrogels, or the preparation of PLA/PGA polymers coupled to water soluble or water dispersible hydrophilic polymers. Thus, even if De Jong *et al.* and Brannon-Peppas were combined, the combination does not provide a process for the preparation of hydrogels, comprising two water soluble or water dispersible hydrophilic polymers grafted with chiral oligomers having complementary chirality, as provided by claims 15-17 of the present invention.

Accordingly, claims 15-17 are nonobvious under De Jong *et al.*, in view of Brannon-Peppas. Applicants respectfully request that this rejection be withdrawn.

Objection under 37 CFR 1.75(c)

Claim 22 is objected to as being in improper multiple dependent form. Claim 22 is cancelled herein. Accordingly, this basis of rejection may be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 313632001000. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By: /Leslie A. Robinson/
Leslie A. Robinson
Registration No.: 54,403
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
(858) 314-7692